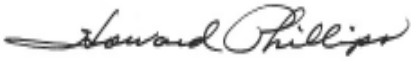
Response to the letter (dated March 6, 2008) received from the EPA

By Phillips Company

3-8-08



Howard Phillips
Email: hp@valliant.net
www.PhillipsCompany.4T.com
"Take it to the people"

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Executive summary

The estimated cost of compliance (for the items listed in the EPA letter) is $650,000.

This cost appears to be beyond the means of Phillips Company. Given these circumstances, we have modified the claims for our product, and the proposed wording for the label of our product, for the purpose of reducing the requirement for additional data and therefore receiving approval for EPA registration of our product.

The EPA letter to which we are responding notes that "Your proposed product label makes claim against Staphylococcus Aureus and Methicillin Resistant *Staphylococcus aureus* (MRSA), which are known public health organisms." In our revised label, described later in this document, we have eliminated any reference to staph or MRSA. Our revised claim does not include the claim that our product will kill any specific bacteria. We only claim that it will "kill bacteria." As stated in the wording for our revised label, our only antimicrobial claim is in the directions for use of the product, "spray evenly until a very thin spray covers room surfaces to kill bacteria." The test data submitted in this document supports this claim. The data is for MRSA, but we make no MRSA-specific claim on our new label.

SDBS = Sodium dodecylbenzene sulfonate, CAS 25155-30-0, is the only active ingredient in our product. We have submitted data to prove that we can obtain a total inhibition zone (kills 100% of the bacteria) for SDBS concentrations of 1% or greater in water. In these tests, the drop zone (when the SDBS liquid was dropped into the Pietri dish) was about 10 mm. It is important to note that the kill zone is 2, 3 or 4 times larger than diameter for SDBS concentrations ranging from 2% to 4%. The MIC (minimum inhibitory concentration of SDBS) is approximately 1% as shown by these data. The SDBS concentration in our StaphWash Room Shield product is 2.7% to ensure effectiveness in killing bacteria.

We believe acute toxicity is not a problem for our only active ingredient. The rationale for this argument is that any acute toxicity problem associated with our only active ingredient surely would have been noted during the use of so many commercial products which contain this active ingredient. More than 35 commercial products use sodium dodecylbenzene sulfonate, also called SDBS. This ingredient has been used in solid, granular, liquid and powder forms in a wide range of commercial products intended for personal care and a wide range of other uses involving human skin contact. Therefore, we reason that chemical state changes (from liquid to solid, for example) involve no risks associated with acute toxicity.

The EPA letter requires "If you do not submit the required data by March 14, 2008, the Agency will administratively withdraw your application on March 19, 2008. Once the application is administratively withdrawn, you will need to submit a new application to the Agency and will be subject to a new PRIA fee." We are responding in a timely manner to meet this deadline.

We ask that the additional data provided herein be accepted as a basis for EPA withdrawing requirements stated in the EPA letter. If additional information or rationale is needed, we will be pleased to respond to EPA requests and directions to the very best of our ability.

Sincerely,

/s/ Howard Phillips
Email: hp@valliant.net
www.PhillipsCompany.4T.com
"Take it to the people"

Letter received from EPA

Dear Mr. Phillips, please see attached letter.

(See attached file: 84995-R Incomplete Appl Letter 28-FEB-2008.doc)
(Embedded image moved to file: pic15435.jpg)

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

==========

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

March 6, 2008

OPP Decision Number: D-389993

Howard Phillips, Ph. D.
Phillips Company
311 Chickasaw Street
Millerton, OK 74750

Subject: Application for Registration
Product Name: Staph Wash Room Shield
EPA File Symbol: 84995-R
Application Date: 19-Feb-2008
EPA Receipt Date: 19-Feb-2008

Dear Dr. Phillips:

The Agency has completed its initial contents screen of your application pursuant to Section 33(f) (4) (B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended the Pesticide Registration Improvement Renewal Act. The Agency has determined that your application did not pass the initial contents screen and therefore must be rejected for the following reasons:

1. Your proposed product label makes claim against Staphylococcus Aureus and Methicillin Resistant *Staphylococcus aureus* (MRSA), which are known public health organisms. Your application contains a 4 page report entitled "Disinfectant Development Specialists Microbiology Study Report" conducted by Antimicrobial Test Laboratories, LLC 2007 for proof of efficacy. No actual efficacy data were submitted with the subject application. Therefore, you must submit efficacy data to support the proposed claims. Please refer to the EPA Antimicrobial Science Policies Disinfectant Technical Science Section (DIS/TSS) 1 and 5 for guidance of current efficacy-related requirements and/or policy for a category of antimicrobial pesticide products, claims, or patterns of use. Please refer to the following website ***http://www.epa.gov/oppad001/sciencepolicy.htm*** for detailed information. If more guidance is needed, you should contact the Antimicrobials Division for further consultation.

2. The information submitted in support of registration for the proposed product failed to satisfy the product chemistry data requirements. Product chemistry data must be conducted on the proposed product formulation under the OPPTS Test Guidelines Series § 830 [PARTS A and B], and submitted to the EPA for review and acceptance to support your registration. Please refer to 40 CFR, Part § 158.150-190 for detailed information.

3. Your proposed product is not substantially similar or identical to another EPA registered product, not only percent active and inert ingredient, but also the same use directions as another currently registered product with respect to acute toxicity data requirements. You must provide the EPA Registration Number of the currently registered product you believe is substantially similar or identical to your product. If you can not find another EPA registered product that is substantially similar or identical to your product, you must conduct the acute toxicity data on your proposed formulation and submit the acute toxicity data for review and acceptance to support the registration of your proposed product. Refer to 40 CFR Part § 158.740 for acute toxicity data requirements.

4. EPA forms 8570-4 [confidential statement of formula], 8570-27 [formulator's exemption], and 8570-35 [data matrix] can not be change [changed]. The forms must be full [filled] out, signed and dated without adding addition [additional] information to the forms. If you need to add additional information, you may submit it as an attachment to [the] forms.

5. The labeling submitted with your application is incomplete. Please refer to the label review manual for assistance. You may obtain a copy of the label review manual at the following website: ***http://www.epa.gov/oppfead1/labeling/lrm/.*** In addition, please refer to 40 CFR Part §156.10.

Note that 40 CFR § 160 set forth the good laboratory practices (GLP) for conducting studies to support applications for registration. The data must be in compliance with the GLP standards and

formatted in accordance with PR notice 86-5.

You may resolve the issue(s) identified in the attached Report by submitting the information to fix the studies by March 14, 2008. Once the corrections have been made, and the subject data passes the 86-5 screen, the Agency will be able to process your action further.

If you do not submit the required data by March 14, 2008, the Agency will administratively withdraw your application on March 19, 2008. Once the application is administratively withdrawn, you will need to submit a new application to the Agency and will be subject to a new PRIA fee.

Please respond to this letter by March 14, 2008 by contacting me by telephone at (703) 308-6422 or by e-mail at *heyward.adam@epamail.epa.gov* during the hours of 8:00 am to 4:00 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

Adam Heyward
Product Manager 34
Regulatory Management Branch II
Antimicrobials Division (7510P)

Response to Paragraph 1 of the EPA letter

Restatement of paragraph

1. Your proposed product label makes claim against Staphylococcus Aureus and Methicillin Resistant *Staphylococcus aureus* (MRSA), which are known public health organisms. Your application contains a 4 page report entitled "Disinfectant Development Specialists Microbiology Study Report" conducted by Antimicrobial Test Laboratories, LLC 2007 for proof of efficacy. No actual efficacy data were submitted with the subject application. Therefore, you must submit efficacy data to support the proposed claims. Please refer to the EPA Antimicrobial Science Policies Disinfectant Technical Science Section (DIS/TSS) 1 and 5 for guidance of current efficacy-related requirements and/or policy for a category of antimicrobial pesticide products, claims, or patterns of use. Please refer to the following website ***http://www.epa.gov/oppad001/sciencepolicy.htm*** for detailed information. If more guidance is needed, you should contact the Antimicrobials Division for further consultation.

Applicable regulatory documentation (Please see Appendix 1)

We have revised our label to meet EPA standards

Our response to paragraph 1 of the EPA letter is as follows:

1. We agree that our label, as submitted with the original application, is too long and not the best. We used a model and sample that was provided by a university.

2. Our new approach to labeling is more straightforward. For our model template, we have used an existing antimicrobial product that is in sold commercially in WalMart, CVS and other stores , and is registered with the EPA. The product is Febreze. The label for this product carries EPA registration information (EPA Reg. No. 3753-69 EPA Est. No. 3573-MO-1) [For additional related information, please see our response to Paragraph 5 of the EPA letter].

3. The EPA letter to which we are responding notes that "Your proposed product label makes claim against Staphylococcus Aureus and Methicillin Resistant *Staphylococcus aureus* (MRSA), which are known public health organisms." In our revised label, we have eliminated any reference to staph or MRSA. We make FEWER claims than Febreze makes on the label. [For additional related information, please see our response to Paragraph 5 of the EPA letter].

Data to support the only claim made on our label

As stated in the wording for our revised label, our only antimicrobial claim is "spray evenly until a very thin spray covers room surfaces to kill bacteria." We are submitting data in this document to support this claim. The data is for MRSA, but we make no MRSA-specific claim on our new label. [For additional related information, please see our response to Paragraph 5 of the EPA letter].

Additional data Waiver Request

For any other possible data envisioned, we request a waiver for the following two reasons:

1. This product uses a single active ingredient, sodium dodecylbenzene sulfonate (SDBS). More than 35 commercial products (listed on subsequent pages of this document) contain this ingredient.

2. EPA considers our active ingredient safe. Reference: "Environmental Fate Assessment of Alkylbenzene Sulfonates for the Registration." Following is the complete document, available online. Go to http://www.regulations.gov and then search for Document ID: EPA-HQ-OPP-2006-0156-0021

Request for acceptance of the above additional information as a basis for EPA withdrawing requirements stated in paragraph 1 of the EPA letter

We ask that the additional data provided above be accepted as a basis for EPA withdrawing requirements stated in paragraph 1 of the EPA letter. If additional information or rationale is needed, we will be pleased to respond to EPA requests and directions.

Response to Paragraph 2 of the EPA letter

Restatement of paragraph

2. The information submitted in support of registration for the proposed product failed to satisfy the product chemistry data requirements. Product chemistry data must be conducted on the proposed product formulation under the OPPTS Test Guidelines Series § 830 [PARTS A and B], and submitted to the EPA for review and acceptance to support your registration. Please refer to 40 CFR, Part § 158.150-190 for detailed information.

Applicable regulatory documentation (Please see Appendix 2)

A review of the test requirements outlined in Appendix 2 leads to the following conclusions:

1. A consultant would be needed if extensive testing were needed.

2. A "for hire" test lab would be needed. The test lab would probably be a SPECIALIZED (expensive) facility.

A consultant might be someone like ...

Michael Weaver, PhD
Professor & Director
Virginia Tech Pesticide Programs
34 Agnew Hall
Blacksburg, VA 24601
540-231-6543
mweaver@vt.edu

Mike Weaver is a Professor in the Department of Entomology at Virginia Tech. He has served as director of Virginia Tech Pesticide Programs (pesticide coordinator) since 1980. His training is in biology, plant pathology, and pest management. He received a B.S. from Edinboro University of Pennsylvania (1974), M.S. from West Virginia University (1977) and PhD. from Virginia Tech (1982). Weaver's primary work is in Extension/outreach in the areas of pesticide safety education and pesticide management. His research involves the environmental and health impacts of pesticides and regulatory impact assessment on pesticide use. He also teaches in the undergraduate and graduate programs at Virginia Tech. The strengths of Virginia Tech's pesticide safety education program include hands-on training, online training, electronic educational media, and train-the-trainer education. For 15 years, the program has held an annual one-to-two-day train-the-trainer workshop for Extension agents. That program has taken on a conference format with multiple sessions, exhibits, and keynote speakers. It is routinely attended by over 85 agricultural agents who conduct training in more than 100 Virginia localities.

Retaining a consultant like this might cost (just guessing) something like $50,000 if the consultant acted as an advisior only (not doing any testing). In addition, a professional test lab would be needed at an approximate cost of $150,000.

Our solution to this problem is to revise our product claims

The level of cost (estimated above) exceeds the net worth of our small company, making it impossible for our company to comply with the EPA test requirements based on the previous claims for our new product. Our solution to this problem is to revise our product claims and the proposed wording on our product label.

We have revised our label to meet EPA standards

Our response to paragraph 2 of the EPA letter is as follows:

1. We agree that our label, as submitted with the original application, is too long and not the best. We used a model and sample that was provided by a university to draft that original label..

2. Our new approach to labeling is more straightforward. For our model template, we have used an existing antimicrobial product that is in CVS and WalMart stores, and is registered with the EPA. The product is Febreze. The label for this product carries EPA registration information (EPA Reg. No. 3753-69 EPA Est. No. 3573-MO-1) [For additional related information, please see our response to Paragraph 5 of the EPA letter].

3. The EPA letter to which we are responding notes that "Your proposed product label makes claim against Staphylococcus Aureus and Methicillin Resistant *Staphylococcus aureus* (MRSA), which are known public health organisms." In our revised label, we have eliminated any reference to staph or MRSA. We make FEWER claims than Febreze makes on the label. [For additional related information, please see our response to Paragraph 5 of the EPA letter].

Data to support the only claim made on our label

As stated in the wording for our revised label, our only antimicrobial claim is "spray evenly until a very thin spray covers room surfaces to kill bacteria." We are submitting data in this document to support this claim. The data is for MRSA, but we make no MRSA-specific claim on our new label. [For additional related information, please see our response to Paragraph 5 of the EPA letter].

Additional data Waiver Request

For any other possible data envisioned, we request a waiver for the following two reasons:

1. This product uses a single active ingredient, sodium dodecylbenzene sulfonate (SDBS). More than 35 commercial products (listed on subsequent pages of this document) contain this ingredient.

2. EPA considers our active ingredient safe. Reference: "Environmental Fate Assessment of Alkylbenzene Sulfonates for the Registration." Following is the complete document, available online. Go to http://www.regulations.gov and then search for Document ID: EPA-HQ-OPP-2006-0156-0021

Request for acceptance of the above additional information as a basis for EPA withdrawing requirements stated in paragraph 2 of the EPA letter

We ask that the additional data provided above be accepted as a basis for EPA withdrawing requirements stated in paragraph 2 of the EPA letter. If additional information or rationale is needed, we will be pleased to respond to EPA requests and directions.

Response to Paragraph 3 of the EPA letter

Restatement of paragraph

3. Your proposed product is not substantially similar or identical to another EPA registered product, not only percent active and inert ingredient, but also the same use directions as another currently registered product with respect to acute toxicity data requirements. You must provide the EPA Registration Number of the currently registered product you believe is substantially similar or identical to your product. If you can not find another EPA registered product that is substantially similar or identical to your product, you must conduct the acute toxicity data on your proposed formulation and submit the acute toxicity data for review and acceptance to support the registration of your proposed product. Refer to 40 CFR Part § 158.740 for acute toxicity data requirements.

Applicable regulatory documentation (Please see Appendix 3)

Our solution to this problem is to revise our product claims

The level of cost (estimated in Appendix 3) exceeds the net worth of our small company, making it impossible for our company to comply with the EPA test requirements based on the previous claims for our new product. Our solution to this problem is to revise our product claims and the proposed wording on our product label and to provide rationale based on common use of our active ingredient in many household products, many of which possibly are registered with the EPA.

List of commercial products that contain our only active ingredient

The following is a list of currently-available products that contain our only active ingredient (sodium dodecyl benzene sulfonate), showing the Percent of SDBS in the commercial products, when known.

[Please see next page]

Household Products Database

National Institutes of Health
National Library of Medicine
Specialized Information Services

Home | Products | Ingredients | MSDS

Browse Alphabetically | Search

Chemical Information

Chemical Name: **Sodium dodecylbenzenesulfonate**

CAS Registry Number: 025155-30-0

Synonyms: Sodium dodecylbenzenesulfonate; Benzenesulfonic acid, dodecyl-, sodium salt; Dodecylbenzenesulfonic acid, sodium salt; Sodium dodecylphenylsulfonate; Sodium laurylbenzenesulfonate

Information from other National Library of Medicine databases

Health Studies: Human Health Effects from Hazardous Substances Data Bank (HSDB)

Toxicity Information: Search TOXNET

Chemical Information: Search ChemIDplus

Biomedical References: Search PubMed

Products that contain this ingredient

Brand	Category	Form	Percent
Turtle Wax Zip Wax Car Wash	Auto products	liquid	
Armor All Car Wash Wipes	Auto products	wipes	0-20
Espree Wire Wheel Cleaner	Auto products	liquid	
Sundance Car Wash	Auto products	liquid	<25
Westleys Bleche-Wite All Wheel Cleaner	Auto products	liquid	
Westleys Concentrated Car wash	Auto products	liquid	
Westleys Tire Dressing Remover	Auto products	liquid	
Mothers Chrome Polish	Auto products	liquid	
Black Magic All Wheel Cleaner	Auto products	liquid	<10
Smart Soap (Car Wash Plus)	Auto products	liquid	<10
Westleys Bleche Wite (Ready to Use)	Auto products	pump spray	
Westleys Megaconcentrate Car wash	Auto products	liquid	20-30
Westleys Wash n Wax	Auto products	liquid	
Toilet Duck Automatic with Bleach	Home inside	tablet	45-60
Dynamo Ultra Power	Home inside	liquid	8
Mr Muscle Pot & Pan Detergent	Home inside	liquid	15-40
Arm & Hammer Ultra Liquid Detergent	Home inside	liquid	1-10
Palmolive Original Hand Dishwashing Liquid	Home inside	liquid	5.3
Ty D Bol Fresh Tabs 2 In 1, Blue	Home inside	tablet	24-33

Household Products Database

National Institutes of Health
National Library of Medicine
Specialized Information Services

Home | Products | Ingredients | MSDS

Browse Alphabetically | Search

Chemical Information

Chemical Name: Sodium dodecylbenzenesulfonate
CAS Registry Number: 025155-30-0
Synonyms: Sodium dodecylbenzenesulfonate; Benzenesulfonic acid, dodecyl-, sodium salt; Dodecylbenzenesulfonic acid, sodium salt; Sodium dodecylphenylsulfonate; Sodium laurylbenzenesulfonate

Zep Tile and Terrazzo Cleaner-04/08/2002	Home inside	liquid	1-10
Woolite Gentle Cycle Original Powder	Home inside	powder	20-25
Lime A Way Automatic Toilet Bowl Cleaner	Home inside	solid	8-12
Giant Pure Power Auto Dish Detergent Lemon 45 OZ BOX	Home inside	granular solid	10-25
Ajax Scouring Cleanser	Home inside	powder	1.7
Sparkle Metal Polisher	Home inside	paste	
Arm & Hammer Concentrated Detergent	Home inside	liquid	1-10
Vanish Hang Ins Automatic Toilet Bowl Cleaner	Home inside	tablet	40-60
Arm & Hammer Liquid Detergent, Sensitive Skin Formula	Home inside	liquid	1-10
Arm & Hammer Liquid Detergent with Color Safe Bleach Alternate	Home inside	liquid	1-10
Woolite Original Fabric Wash	Home inside	liquid	1-10
Woolite Gentle Cycle Fabric Wash, Liquid, All Scents	Home inside	liquid	5-10
Westleys Concentrated Bleche-Wite	Home inside	liquid	2-10
Giant Auto Dish Detergent 75 OZ BOX	Home inside	granular solid	10-25
Red Devil Garage and Driveway Cleaner	Home maintenance	powder	2
Zep Commercial Patio Furniture Cleaner	Landscaping/Yard	liquid	<3
Zep Commercial Patio Furniture Cleaner-05/24/1999	Landscaping/Yard	liquid	<3
Caress Moisturizing Deodorant Body Bar-Shower Fresh	Personal care/use	solid	
Caress Moisturizing Body Bar with Bath Oil	Personal care/use	solid	
Dove Soap Bar with 1/4 Moisturizing Lotion	Personal care/use	solid	

We believe acute toxicity is not a problem for our only active ingredient

We believe acute toxicity is not a problem for our only active ingredient. The rationale for this argument is that any acute toxicity problem associated with our only active ingredient surely would have been noted during the use of so many commercial products which contain this active ingredient. More than 35 commercial products use our active ingredient (sodium dodecylbenzene sulfonate, also called SDBS). This ingredient has been used in solid, granular, liquid and powder forms in a wide range of commercial products intended for personal care and a wide range of other uses involving human skin contact. Therefore, we reason that chemical state changes (from liquid to solid, for example) involve no risks associated with acute toxicity.

Additional data Waiver Request

For any other possible data envisioned, we request a waiver for the following two reasons:

1. This product uses a single active ingredient, sodium dodecylbenzene sulfonate (SDBS). More than 35 commercial products (listed abovet) contain this ingredient.

2. EPA considers our active ingredient safe. Reference: "Environmental Fate Assessment of Alkylbenzene Sulfonates for the Registration." Following is the complete document, available online. Go to http://www.regulations.gov and then search for Document ID: EPA-HQ-OPP-2006-0156-0021

3. Many of the household products listed on the previous pages contain a concentration greater than the concentration in our planned product. The SDBS concentration in our planned product is 2.5%, whereas the SDBS concentration is twice that amount (5.3%) in one commercial product being sold for hand dishwashing use. This is shown by the data below, taken from the tables on the previous two pages:

Arm & Hammer Ultra Liquid Detergent	Home inside	liquid	1-10
Palmolive Original Hand Dishwashing Liquid	Home inside	liquid	5.3

Request for acceptance of the above additional information as a basis for EPA withdrawing requirements stated in paragraph 3 of the EPA letter

We ask that the additional data provided above be accepted as a basis for EPA withdrawing requirements stated in paragraph 3 of the EPA letter. If additional information or rationale is needed, we will be pleased to respond to EPA requests and directions.

Response to Paragraph 4 of the EPA letter

Restatement of paragraph

4. EPA forms 8570-4 [confidential statement of formula], 8570-27 [formulator's exemption], and 8570-35 [data matrix] can not be change [changed]. The forms must be full [filled] out, signed and dated without adding addition [additional] information to the forms. If you need to add additional information, you may submit it as an attachment to [the] forms.

We agree with this requirement. In accordance with this requirement, please consider the information in this document to be attachments to any applicable parts of the forms previously submitted.

Response to Paragraph 5 of the EPA letter

Restatement of paragraph

5. The labeling submitted with your application is incomplete. Please refer to the label review manual for assistance. You may obtain a copy of the label review manual at the following website: ***http://www.epa.gov/oppfead1/labeling/lrm/.*** In addition, please refer to 40 CFR Part §156.10.

Applicable regulatory documentation (Please see Appendix 5)

We have revised our label to meet EPA standards

Our response to paragraph 5 of the EPA letter is as follows:

1. We agree that our label, as submitted with the original application, is too long and not the best. We used a model and sample that was provided by a university.

2. Our new approach to labeling is more straightforward. For our model template, we have used an existing antimicrobial product that is in every WalMart store, and is registered with the EPA. The product is Febreze. The label for this product carries EPA registration information (EPA Reg. No. 3753-69 EPA Est. No. 3573-MO-1)

3. The EPA letter to which we are responding notes that "Your proposed product label makes claim against Staphylococcus Aureus and Methicillin Resistant *Staphylococcus aureus* (MRSA), which are known public health organisms." In our revised label, described below, we have eliminated any reference to staph or MRSA. We make FEWER claims than Febreze makes on the label.

The antimicrobial product that we have selected as our model is shown below.

Wording for commercial product with a FRONT label that has been accepted by EPA

Wording for our planned product FRONT label, hereby submitted to EPA for approval

StaphWash Room Shield

Antimicrobial

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for other precautions.

Active ingredient: Sodium dodecylbenzene sulfonate 2.7%

Other ingredients: 97.3%

3740 mL (1 gallon)

128 FL OZA magnified photograph of the front label of this product is shown below.

Wording for commercial product with a BACK label that has been accepted by EPA

Wording for our planned product BACK label, hereby submitted to EPA for approval

StaphWash Room Shield

Antimicrobial

DIRECTIONS FOR USE: It is a violation of Federal law to use this product in a manner inconsistent with its labeling. From a distance of 6 to 8 inches spray evenly until a very thin spray covers room surfaces to kill bacteria. Allow surfaces to dry before resuming normal use. SAFETY: Will not harm most fabrics and hard surfaces. Before using this product on questionable materials, spray product on a small test area to demonstrate acceptable results. Reapply as needed.

CAUTION: Avoid contact with eyes. FIRST AID: IF IN EYES, hold eyelids open and rinse slowly and gently with water for 15-20 munutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eyes. Call a poison control center or see a physician for treatment advice.

STORAGE AND DISPOSAL: Store at room temperature. Discard empty container in trash. Contains no phosphates; no alcohol; no biological products. EPA Reg. No. 84995.

QUESTIONS? 1 580 746-2430.

MADE IN USA. Mfg. by Phillips Company, Millerton, OK 74750. Patents pending.

Data to support the only claim made on our label

As stated in the wording for our revised label, our only antimicrobial claim is “spray evenly until a very thin spray covers room surfaces to kill bacteria.” The following data supports this claim. The data is for MRSA, but we make no MRSA-specific claim on our new label.

Antimicrobial Testing

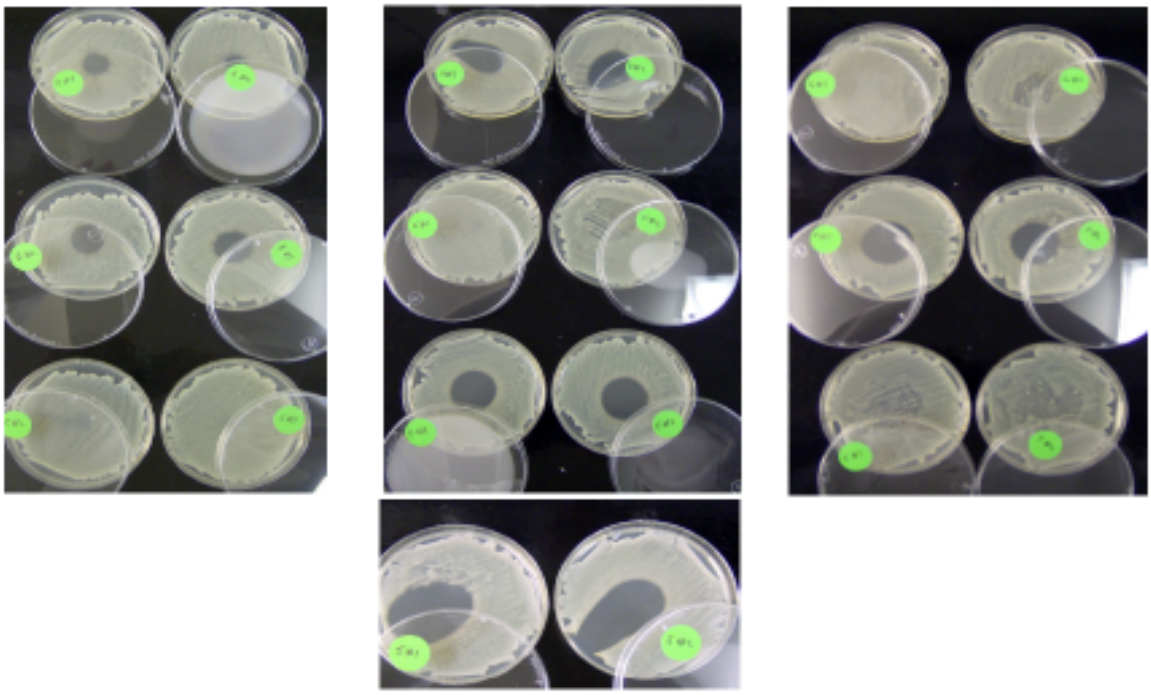
AntimicrobialTestLaboratories LLC

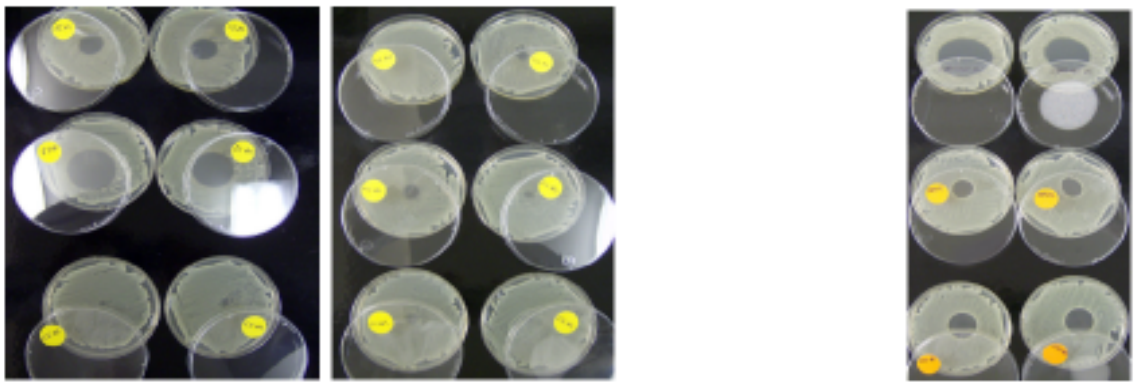
Disinfectant Development Specialists

Microbiology Study Report

Page 4 of 4

Photos of MRSA Plates After 24 Hour Incubation





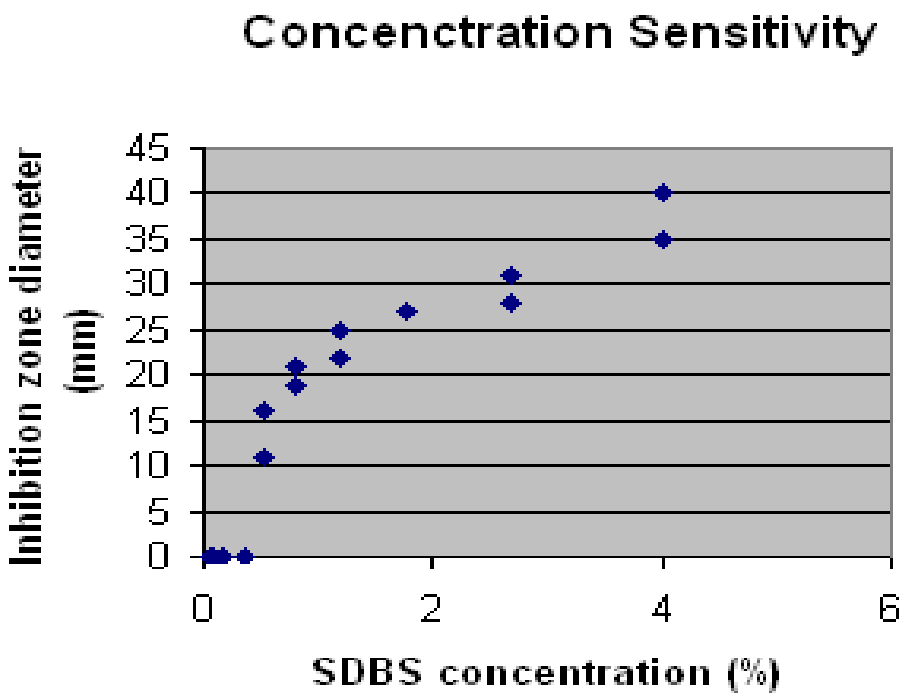
39 California Avenue
Suite 302
Pleasanton, CA 94566

Phone: (925) 485-4332
E-Mail: info@AntimicrobialTestLabs.com
Web site: http://www.AntimicrobialTestLabs.com

Antimicrobial effectiveness vs. active ingredient (SDBS) concentration

EXPERIMENT 1 -- Purpose of experiment: Investigate linearity of the effectiveness of SW as a killer of staph bacteria.

Inhib zone (mm)	(mm)	Samp Sort #	Vol of SW mix	Vol water	% SDBS conc	Samp Vol	Samp Label
35	40	1			4.00%	3	J
31	28	2	6	3	2.67%	3	H
27	27	3	6	3	1.78%	3	F
22	25	4	6	3	1.19%	3	D
19	21	5	6	3	.790%	3	B
16	11	6	6	3	.527%	3	A
0	0	7	6	3	.351%	3	C
0	0	8	3	3	.176%	3	E
0	0	9	3	3	.088%	3	G
0	0	10	3	3	.044%	3	I



In the above data, SDBS = Sodium dodecylbenzene sulfonate, CAS 25155-30-0, the only active ingredient in our product.

Concluisons from test data

These data prove that we can obtain a total inhibition zone (kills 100% of the bacteria) for SDBS concentrations of 1% or greater. The MIC (minimum inhibitory concentration of SDBS) is approximately 1% as shown by these data.

The drop zone (when the SDBS liquid was dropped into the Pietri dish) was about 10 mm. It is important to note that the kill zone is 2, 3 or 4 times larger than diameter for SDBS concentrations ranging from 2% to 4%.

Request for acceptance of the above additional information and revised claims and label wording as a basis for EPA withdrawing requirements stated in paragraph 5 of the EPA letter

We ask that the additional data provided above be accepted as a basis for EPA withdrawing requirements stated in paragraph 2 of the EPA letter. If additional information or rationale is needed, we will be pleased to respond to EPA requests and directions.

Summary and conclusions

The estimated cost of compliance (for the items mentioned in the EPA letter) is $650,000.

This cost appears to be beyond the means of Phillips Company. Given these circumstances, we have modified the claims for our product, and the proposed wording for the label of our product, for the purpose of reducing the requirement for additional data and therefore receiving approval for EPA registration of our product.

The EPA letter to which we are responding notes that "Your proposed product label makes claim against Staphylococcus Aureus and Methicillin Resistant *Staphylococcus aureus* (MRSA), which are known public health organisms." In our revised label, described previously in this document, we have eliminated any reference to staph or MRSA. Our revised claim does not include the claim that our product will kill any specific bacteria. We only claim that it will "kill bacteria." As stated in the wording for our revised label, our only antimicrobial claim is "spray evenly until a very thin spray covers room surfaces to kill bacteria." The test data submitted in this document supports this claim. The data is for MRSA, but we make no MRSA-specific claim on our new label.

SDBS = Sodium dodecylbenzene sulfonate, CAS 25155-30-0, is the only active ingredient in our product. We have submitted data to prove that we can obtain a total inhibition zone (kills 100% of the bacteria) for SDBS concentrations of 1% or greater. The drop zone (when the SDBS liquid was dropped into the Pietri dish) was about 10 mm. It is important to note that the kill zone is 2, 3 or 4 times larger than diameter for SDBS concentrations ranging from 2% to 4%. The MIC (minimum inhibitory concentration of SDBS) is approximately 1% as shown by these data. The SDBS concentration in our Staph-Wash Room Shield product is 2.7% to ensure effectiveness in killing bacteria.

The EPA letter requires "If you do not submit the required data by March 14, 2008, the Agency will administratively withdraw your application on March 19, 2008. Once the application is administratively withdrawn, you will need to submit a new application to the Agency and will be subject to a new PRIA fee." We are responding in a timely manner to meet this deadline.

We ask that the additional data provided herein be accepted as a basis for EPA withdrawing requirements stated in the EPA letter. If additional information or rationale is needed, we will be pleased to respond to EPA requests and directions.

Howard Phillips
Email: hp@valliant.net
www.PhillipsCompany.4T.com
"Take it to the people"

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Appendix 1

Regluatory documentation relative to Para. 1 of the EPA letter

Disinfectants for Use on Hard Surfaces

DIS/TSS-1 Jan 22, 1982
EFFICACY DATA REQUIREMENTS
Disinfectants for Use on Hard Surfaces

(a) **Limited efficacy claims.** The label of a disinfectant which is effective against a specific major group of microorganisms only (e.g., Gram-positive or Gram-negative) must specify the major group against which it is effective.

The basic StaphWash Room Shield is effective against Gram-positive bacteria.

(1) **Test requirements.** The AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products) is required. Sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against **Salmonella choleraesuis** ATCC 10708 (for effectiveness against Gram-negative bacteria) or **Staphylococcus aureus** ATCC 6538 (for effectiveness against Gram-positive bacteria). (Sixty carriers per sample; a total of 180 carriers.)
(2) **Performance requirements.** To support products represented in labeling as "disinfectants", killing on 59 out of each set of 60 carriers is required to provide effectiveness at the 95% confidence level.
(b) **General or broad-spectrum efficacy claims.** Label claims of effectiveness as a "general disinfectant" or representations that the product is effective against a broad spectrum of microorganisms are acceptable if the product is effective against both Gram-positive and Gram-negative bacteria.
(l) **Test requirements.** Use the AOAC Use-Dilution Method or the AOAC Germicidal Spray Product Test as in (a)(l). Sixty carriers must be tested against each of both S. choleraesuis and S. aureus with each of 3 samples, representing 3 different batches, one of which is at least 60 days old. (120 carriers per sample; a total of 360 carriers.)

360 carriers would involve a cost of $1800.

The EPA letter requires "If you do not submit the required data by March 14, 2008, the Agency will administratively withdraw your application on March 19, 2008. Once the application is administratively withdrawn, you will need to submit a new application to the Agency and will be subject to a new PRIA fee." It is impossible to prepare samples with a 60-day age history in the length of time allowed by the EPA for the required data.

(2) **Performance requirements.** Same as in (a)(2) above.
(c) **Hospital or medical environment efficacy claims.** Label claims for use of disinfectants in Hospital or medical environments are acceptable only for those products that are effective for general or broad-spectrum disinfection and additionally against the nosocomial bacterial pathogen **Pseudomonas aeruginosa.**

This additional test requirement is for 120 samples, at an additional cost of $600.

(l) **Test requirements.** Employ the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products Test as in (a)(l). Sixty carriers must be tested against each of S. **choleraesuis**, S. **aureus**, and **Pseudomonas aeruginosa** ATCC 15442 with each of 3 samples, representing, one of which is at least 60 days old. (180 carriers per sample; a total of 540 carriers.)
(2) **Performance requirements.** Same as in (A)(2) above.
(d) **Other microorganisms.** Substantiated label claims of effectiveness of a disinfectant against specific microorganisms other than the designated test microorganism(s) are permitted, but not required, provided that the target pest **is likely to be present** in or on the recommended use areas and surfaces and thus may present a potential problem.
(1) **Test requirements.** Effectiveness of disinfectants against specific microorganisms other than those named in the AOAC Use Dilution Method, AOAC Germicidal Spray Products Test, AOAC Fungicidal Test, and AOAC Tuberculocidal Activity Method (II. Confirmative In-Vitro Test), but not including viruses, must be determined by either the AOAC Use-Dilution Method or the AOAC Germicidal Spray Products Test as in (a)(l). Ten carriers must be tested against each specific microorganism with each of 2 samples, representing 2 different batches. (10 carriers per sample, a total of 20 carriers.)
(2) **Performance requirements.** Killing of the test microorganism on all carriers is required. Plate count data, on appropriate culture media, must be submitted on each test microorganism to disclose that a concentration of at least 10^4 microorganisms survive the carrier-drying step in order to provide meaningful results.

This is an additional cost, estimated to be $2 per sample; 360 + 120 = 480 samples; for an additional estimated cost of $960.

Total cumulative cost so far = $3360.

Confirmatory Efficacy Data Requirements

DIS/TSS-5 Sept. 22, 1982
CONFIRMATORY EFFICACY DATA REQUIREMENTS

1. When Applicable. In certain situations an applicant is permitted to rely on previously submitted efficacy data to support an application or amendment for registration of a product and to submit only minimal confirmatory efficacy data on his own product to demonstrate his ability to produce an effective formulation. These situations are as follows:

a. **Duplicated Product Formulations.** In this situation, the applicant manufactures a formulation which duplicates a product that is already registered with complete supporting efficacy data. The chemical composition, manufacturing procedure, label claims, and directions for use are identical in substance to those of the original registration, and specific references to the supporting data developed for the original product are furnished by the applicant.

b. **Minor Formulation Change in a Registered Product.** In this situation, the change in the formulation is relatively minor, e.g., a change of an inert ingredient. The label claims and directions for use are unchanged from those accepted for the registered formulation, and specific references to the supporting data developed for the original formulation are cited by the regis-

trant.

2. Confirmatory Data Required. The following data must be developed on the applicant's own finished product. When the test methodology utilized in deriving the original supporting efficacy data were modified to include additional elements not specified in the recommended method, such as organic soil, hard water, longer or shorter contact time, etc., the confirmatory data must be produced under similarly modified conditions. The specified confirmatory data are required to be developed only at the dilution and condition which represents the highest level of efficacy and most stringent condition claimed on the label, e.g., as a hospital disinfectant in organic soil for a product which may be used at different dilutions for hospital or general disinfection or in the presence or absence of organic soil, or additionally as a sanitizing rinse for food contact surfaces.

a. **Disinfectants for Use in Hospital or Medical Environments.** (i) **Test Requirements.** Ten carriers on each of 2 samples representing 2 different batches are required against each of Salmonella choleraesuis ATCC 10708, Staphylococcus aureus ATCC 6538, and Pseudo**monas aeruginosa** ATCC 15442, employing the AOAC Use-Dilution Method for liquid products, or the AOAC Germicidal Spray Products Test for spray products.

(ii) **Performance Standard.** Killing on all carriers is required.

b. **General Broad-Spectrum Disinfectants.** (i) **Test Requirements.** Ten carriers on each of 2 samples representing 2 different batches are required against each of S. choleraesuis and S. aureus, employing the AOAC Use-Dilution Method for liquid products, or the AOAC Germicidal Spray Products Test for spray products.

(ii) **Performance Standard.** Killing on all carriers is required.

c. **Disinfectants with Limited Efficacy.** (i) **Test Requirements.** Ten carriers on each of 2 samples representing 2 different batches are required against either S. choleraesuis or S. aureus, depending upon the microorganism against which the activity of the product is limited, employing the AOAC Use-Dilution Method for liquid products, or the AOAC Germicidal Spray Products Test for spray products.

(ii) **Performance Standard.** Killing on all carriers is required.

d. **Sanitizing Rinses for Food-Contact Surfaces.** (i) **Test Requirements.** One test on one sample, with or without hard water (depending on the label claim), is required using either: the AOAC Germicidal and Detergent Sanitizers Method against **Escherichia coli** ATCC 11229 for quaternary ammonium compounds, chlorinated trisodium phosphate, and anionic detergent-acid formulations; or the AOAC Available Chlorine Germicidal Equivalent Concentration Test against **Salmonella typhi** ATCC 6539 for iodophors, mixed halides, and chlorine-bearing chemicals.

(ii) **Performance Standard.** (A) **AOAC Germicidal Detergent Sanitizers Method.** Acceptable results must show a 99.999% reduction in the number of microorganisms within 30 seconds. The results must be reported as the actual counts and the percentage reduction over the control.

(B) **AOAC Available Chlorine Germicidal Equivalent Concentration Test.** Test results must show product concentrations equivalent in activity to 50, 100, and 200 ppm of available chlorine. (The reference standard is sodium hypochlorite.)

Note: For pressurized spray disinfectants, certification is required that all parts and materials used in the

aerosol container are identical to those specified for the original product.

3. When Not Applicable. Products proposed for registration which are merely relabeled, repackaged, or simple dilutions of a product already registered and manufactured by another registrant require only documentation of this identity and specific references to the supporting data developed for the original product. Confirmatory test data are not required for these situations. For use patterns other than disinfectants and sanitizers as specified above, required bridging data will be determined (or waived) on a case-by-case basis.

Appendix 2

Regluatory documentation relative to Para. 2 of the EPA letter

One problem with the following is that PART A and PART B are not identified.

United States
Environmental Protection
Agency
Prevention, Pesticides
and Toxic Substances
(7101)
EPA 712–C–96–151
April 1996

Ecological Effects Test Guidelines -- OPPTS 850.4000

Background—Nontarget

Plant Testing

"Public Draft"
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INTRODUCTION
This guideline is one of a series of test guidelines that have been developed by the Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency for use in the testing of pesticides and toxic substances, and the development of test data that must be submitted to the Agency for review under Federal regulations.
The Office of Prevention, Pesticides and Toxic Substances (OPPTS) has developed this guideline through a process of harmonization that

blended the testing guidance and requirements that existed in the Office of Pollution Prevention and Toxics (OPPT) and appeared in Title 40, Chapter I, Subchapter R of the Code of Federal Regulations (CFR), the Office of Pesticide Programs (OPP) which appeared in publications of the National Technical Information Service (NTIS) and the guidelines published by the Organization for Economic Cooperation and Development (OECD).

The purpose of harmonizing these guidelines into a single set of OPPTS guidelines is to minimize variations among the testing procedures that must be performed to meet the data requirements of the U. S. Environmental Protection Agency under the Toxic Substances Control Act (15 U.S.C. 2601) and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136, *et seq.*).

Public Draft Access Information: This draft guideline is part of a series of related harmonized guidelines that need to be considered as a unit. *For copies:* These guidelines are available electronically from the EPA Public Access Gopher (gopher.epa.gov) under the heading ‘‘Environmental Test Methods and Guidelines’’ or in paper by contacting the OPP Public Docket at (703) 305–5805 or by e-mail: guidelines@epamail.epa.gov.

To Submit Comments: Interested persons are invited to submit comments. By mail: Public Docket and Freedom of Information Section, Office of Pesticide Programs, Field Operations Division (7506C), Environmental Protection Agency, 401 M St. SW., Washington, DC 20460. In person: bring to: Rm. 1132, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. Comments may also be submitted electronically by sending electronic mail (e-mail) to: guidelines@epamail.epa.gov.

Final Guideline Release: This guideline is available from the U.S. Government Printing Office, Washington, DC 20402 on *The Federal Bulletin Board*. By modem dial 202–512–1387, telnet and ftp: fedbbs.access.gpo.gov (IP 162.140.64.19), or call 202–512–0135 for disks or paper copies.

This guideline is also available electronically in ASCII and PDF (portable document format) from the EPA Public Access Gopher (gopher.epa.gov) under the heading ‘‘Environmental Test Methods and Guidelines.’’

The above web site and URL are not active.

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OPPTS 850.4000 Background—nontarget plant testing.

(a) **Scope**—(1) **Applicability.** This guideline is intended to meet testing requirements of the Federal Insecticide, Fungicide, and Rodenticide

Act (FIFRA) (7 U.S.C. 136, *et seq.*) and the Toxic Substances Control Act (TSCA) (15 U.S.C. 2601).

(2) **Background.** The source material used in developing this harmonized OPPTS test guideline is OPP 120–1 Overview, 120–2 Definitions, 120–3 Basic Test Standards, and 120–4 General Evaluation and Reporting Requirements (Pesticide Assessment Guidelines, Subdivision J—Hazard Evaluation; Nontarget Plants) EPA report 540/09-82-020, 1982.

(b) **Introduction**—(1) **General.** This guideline provides general information and overall guidance for OPPTS 850, Group D—Nontarget Plants Test Guidelines. Series 850 deals with data submittal to support registration of all outdoor use pesticides that come in contact with plants and addresses testing for adverse pesticidal effects to nontarget plants, including those which are within the pesticide application target area (such as crop plants which are growing with weeds or are hosts for insects and disease organisms), and those which are outside the target area (such as typical adjacent crop plants, desirable ornamentals, garden plantings, important wildlife food and cover species, and forestry, lumber, and conservation plantings and endangered and threatened plant species). Series 850 addresses plant toxicity with respect to that resulting from either direct exposure (i.e. application of a pesticide to a plant) or from indirect exposure (i.e. exposure resulting from movement of the pesticide through the environment as from runoff, soil erosion, spray drift, etc.).

(2) **Purpose.** The purpose common to all tests is to provide data which will be used to determine the need for (and support the wording for) precautionary labeling or other statements to minimize the potential adverse effects to nontarget plants. Generally, the registrant will provide adequate precautionary labeling with respect to nontarget plants such as crops, ornamentals, and the like. However, there may be situations where the Agency will have to develop additional precautionary labeling. For example, the spraying of herbicides may not be permitted in the vicinity of critical habitats of endangered or threatened plants listed by the Department of Interior.

(3) **Organization.** (i) This group of guidelines contains two broad areas of testing procedures:

(A) Toxicity to plants in the target area.

(B) Toxicity to plants outside of the target area.

(ii) These data should be derived from tests and reported in a manner which complies with the general test standards and the general reporting requirements contained in this guideline as well as the specific standards

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and reporting requirements of each guideline in OPPTS Series 850, Group D, Nontarget Plants Test Guidelines.

(c) **Definitions.** Terms used in this guideline have the meanings set

forth in FIFRA at Part 162.3, section 3 regulations, and OPPTS guideline 810.1100 (for target area phytotoxicity testing). In addition, for the purposes of this guideline group, the following definitions apply:

Algae includes all chlorophyllous *Thallophyta* other than the *Bryophyta*. It includes the blue-green algae (*Cyanobacterium* or *Cyanophyta*), green algae (*Chlorophyta*), golden algae and diatoms (*Crysophyta*), brown algae (*Phaeophyta*), red algae (*Rhodophyta*), and golden-green algae (*Xanthophyta*).

Aquatic plants includes those plants that are totally aquatic (free-floating or attached, submersed and immersed) and those which are semiaquatic such as swamp and wetland plants.

Axenic is a culture of *Lemna* fronds free from other organisms.

Colony is an aggregate of mother and daughter fronds attached to each other.

Desirable plants are those plants that are not to be detrimentally affected during pesticide application. They may include crops, ornamentals, or wild plants inside or outside of the area of intended application.

ECX is the external pesticide concentration required to cause a detrimental change or alteration (in a nontarget plant) expressed as a percent (X) in comparison to untreated control plants. EC05, EC25, and EC50 are the concentrations required to effect a 5, 25, and 50 percent detrimental change, respectively, on nontarget plant growth or activity.

Endpoints is a measurement during or at the end of a test, or calculated from test data, that may be used to assess the effects of a pesticide on the test organism such as numbers of organisms that survive, percent emergence, visual phytotoxicity, growth rate measurements like plant height, plant dry weight, root dry weight.

Frond is a single *Lemna* leaf-like structure.

Frond mortality are dead fronds which may be identified by a total discoloration (yellow, white, black, or clear) of the entire frond.

LOEC is the lowest test concentration of a material used in this test that has an adverse effect.

Microorganism is any of those organisms classified as algae, fungi (*Myxomycota* and *Eumycota*), and bacteria (*Schizomycota*).

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NOEC is the highest test concentration of a material used in this test that does not have an adverse effect.

Nontarget plant and nontarget microorganism are any plant and

microorganism species not considered to be pests in the location in which they are growing. These species are not intended to be controlled, injured, killed, or detrimentally-affected in any way by a pesticide. Nontarget plants include desirable or pest host plants such as crops or ornamentals within the target area, and desirable plants outside the target area.
Pest-free is as free of pests as reasonably possible. For all pesticide phytotoxicity tests, damaging insects and surrounding weeds should be controlled so that healthy desirable plants are available for testing. With this action detrimental effects can be attributed to the pesticide in question, not to another pesticide, or to weeds, or damaging insects.
Phytotoxicity or plant toxicity are unwanted detrimental deviations from the normal pattern of appearance, growth, and function of plants in response to pesticides and to other toxic chemicals that may be applied with the pesticide. The phytotoxic response may occur during germination, growth, differentiation, and maturation of plants, and may be of a temporary or long-term nature. Phytotoxic responses include adverse effects on growth habit, yield, and quality of plants or their commodities to the extent that a relationship between cause and effect can be established.
Plants comprise vascular and nonvascular plants, algae, and fungi.
Representative end-use product is a pesticide product that is representative of a major formulation category (e.g. emulsifiable concentrate, granular product, wettable powder) and pesticide group (e.g. herbicide, fungicide, insecticide, etc.) and contains the AI of the applicant's product.
Semiaquatic plants are plants living in transition areas between aquatic and dry land areas, e.g., swamps, wetlands.
Static-renewal test is a test method in which the test solution is periodically replaced at specific intervals during the test.
Target area is the area intentionally treated with a pesticide when label use directions are followed.
Target area plants are all plants located within the target area, and includes both desirable and undesirable species.
TEP is a typical end-use product.
TGAI is a technical grade active ingredient.
Terrestrial plants are plants that do not require saturated soils for growth.

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(d) **Nontarget area phytotoxicity testing**—(1) **Data requirements.** Data concerning the determination of outdoor pesticidal effects on nontarget area plants are required for use in ecological risk assessment. (See 40 CFR 158.150.) These data are also of use in assessments of potential

off-target injury to endangered and threatened plant species listed by the Fish and Wildlife Service, Department of Interior, and when phytotoxicity concerns arise from incidents or during Special Review.

(2) **Testing scheme.** Tests in the lower tiers (Guidelines 850.4100 and 850.4400 for Tier I and 850.4200 and 850.4400 for Tier II) are designed to screen chemicals to determine the potential to cause adverse affects on seedling emergence, vegetative vigor, and aquatic plant growth and reproduction. The minimal phytotoxicity data set in Tier I applies to registrations of all pesticides except herbicides, desiccants, defoliants, and plant regulators. These tests apply to all terrestrial, aquatic, and forestry uses so that the Agency can assess the potential for short and long term adverse impacts on terrestrial and aquatic ecosystems and systematically evaluate each pesticide for potential adverse effects to endangered or threatened species. Tier II provides for generation of dose-response testing for outdoor uses of all known phytotoxicants, including, but not limited to herbicides, desiccants, defoliants, plant growth regulators and any fungicides, insecticides or other chemicals tested in Tier I which demonstrate phytotoxicity. In addition, Tier III (Guidelines 850.4300 and 850.4450) is designed to broaden the knowledge concerning any detrimental effects on nontarget plants. Progression to Tier III would occur as needed to evaluate appropriate risk mitigation methods. The criteria to proceed from one tier to the next are given in 40 CFR 158.540.

(3) **Waivers.** Waivers of specific nontarget phytotoxicity test data or protocols may be requested. The request for waiver must address the product application methodology, the pesticide product's biological, chemical, and physical properties, and the known phytotoxic properties of the pesticide product.

(4) **Substitutions.** If the pesticide or the active ingredient (AI) of the pesticide, e.g. herbicide or other phytotoxic pesticide, has been extensively tested using screening tests or other evaluation systems that are similar in intent to any tests of Tier I, the data from those tests may be submitted in lieu of the required data. The term ''extensively tested'' means dose response testing of at least the plants or plant families represented in OPPTS 850.4100 and 850.4400 under environmental conditions suitable to determine any phytotoxic effects. The reports should be submitted as provided in paragraphs (c) of OPPTS 850.4100, 850.4400, 850.4200, 850.4300, and 850.4450. In addition, paragraph (h) of this guideline lists the information to be provided regarding the plant screening data and the documentation to be provided on testing procedures. The Agency will reserve the right to require testing as provided in Tier I if the submitted

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test data do not prove to be adequate to assess a pesticide's phytotoxic nature.

(e) **Target area phytotoxicity testing waiver of requirements.** (1) It has been determined that product performance test data include target

area phytotoxicity testing data (see Guideline 850.4025), and that data submittals for such testing may be waived by the authority of the Administrator, under FIFRA (U.S. Code 7, 136, 3(c)(5), for most kinds of pesticide products. Such products generally include all pesticides whose uses result in direct or indirect application to plants in the target area such as rangelands and nonagricultural areas.

(2) Even though the Administrator will ordinarily waive the requirements for submittal of target areaa phytotoxicity test data as indicated in paragraph (d)(1) of this guideline, the Administrator reserves authority to require such data on a case-by-case basis, whenever the Administrator deems that such data are necessary to evaluate the acceptability of a product.

(f) **Basic test standards**—(1) **Purpose.** This paragraph contains test standards that apply to all studies in this series of guidelines. If a specific test contains a standard on the same subject, that specific test standard should take precedence in the performance of that particular study.

(2) **General.** The experimental design, execution of the experiments, classification of the organism, sampling, measurement, and data analysis in support of an application for registration must be accomplished by use of sound scientific techniques recognized by the scientific community. The uniformity of procedures, materials, and reporting must be maintained throughout the toxicity evaluation process. Refinements of the procedures to increase their accuracy and effectiveness are encouraged. When such refinements include major modifications of any test procedure or standard, the Agency should be consulted before implementation. All references supplied with respect to protocols or other test standards are provided as recommendations.

(3) **Personnel.** (i) All testing and evaluation must be done under the direction of personnel who have the education, training, and/or experience to perform the testing and evaluation in accordance with sound scientific experimental procedures.

(ii) To help assure consistency in the development of data, one person should be responsible for each particular phase of the study.

(4) **Test Substance.** (i) Use of a TEP instead of a TGAI is preferred for all terrestrial nontarget plant phytotoxicity tests. Aquatic plant studies may be conducted using the TEP or TGAI. If an adjuvant is recommended on the product label, representative adjuvants must be included in the test at the recommended dosage. The TEP selected for testing should be the

one with the highest percentage AI and/or the one most widely used. TEP's that contain other AI's should be avoided or tested separately. The use of TEP testing should eliminate the need for a separate solvent control as the solvents will already be contained in the formulation. An untreated

(negative) control is still required. If a carrier, vehicle, or adjuvant is used to dissolve, dilute, or modify the physical characteristics of the test substance for any study, it should not:
(A) Interfere with the metabolism (degradation) of the test substance.
(B) Alter the chemical properties of the test substance.
(C) Produce physiological or toxic effects to plants.
(ii) In addition to or instead of data required by this guideline, the Agency may require, after consultation with the applicant, data derived from testing with:
(A) The technical grade of an AI.
(B) A contaminant or impurity of an active or inert ingredient.
(C) A metabolite or degradation product of an active or inert ingredient.
(D) A different pesticide formulation (TEP).
(E) Any additional substance which enhances the phytotoxic activity (up to and including synergistic effects) of the product for which registration is sought.
(F) Any combination of the test substances listed.
(5) **Nontarget plant test species.** (i) The organism species or groups to be tested are specified in OPPTS 850.4100 through 850.4450.
(ii) Healthy plants must be used.
(iii) Either cultivated crop, ornamental, or wild indigenous plants may be used; endangered or threatened species as determined by the Endangered Species Act of 1973 (Public Law 93–205) are not to be used. When selecting plant test species other than corn, soybean, and a root crop, the Agency encourages the use of sensitive plants other than crop plants—weeds, native species, perennial species, etc. The Agency also encourages testing of more than 10 species.
(iv) Test organisms that are obtained from natural systems and which are to be used for testing should be maintained under conditions similar to their natural or normal cultural environment.
(v) The population size of each replicate or treatment should be large enough to assure meaningful results. Sample sizes should be selected
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which will yield results that are statistically significant at the 90 to 95 percent level of confidence with a significance level of less than 0.10. The sample size for each plant species in the tier tests should be of sufficient size to support the 25 or 50 percent (EC25 or EC50) progression

criteria statistically.
(6) **Nontarget organism safety.** While performing field tests, all necessary measures should be taken to ensure that nontarget plants and animals, especially endangered or threatened species, will not be adversely affected either by direct hazard or by impact on food supply or food chain.
(7) **Controls.** Control groups are used to assure that effects observed are associated or attributed only to the test substance exposure. In phytotoxicity evaluations, all treated plots, plants, and commodities must be compared directly to untreated control plots, plants, and commodities. The appropriate control group should be similar in every respect to the test group except for exposure to the test substance. Within a given study, all test organisms including the controls should be from the same source. To prevent bias, a system of random assignment of the test plants to test and control groups is required. Where a carrier, vehicle, or adjuvant other than water is used, appropriate experiments and controls should be included to distinguish the possible action of the carrier, vehicle, or adjuvant.
(8) **Equipment.** (i) All equipment used in conducting the test, including equipment used to prepare and administer the test substance, and equipment to maintain and record environmental conditions, should be of such design and capacity that tests involving this equipment can be conducted in a reliable and scientific manner. Equipment should be inspected, cleaned, and maintained regularly, and be properly calibrated.
(ii) The application equipment used in testing products in small field plot studies should be designed to simulate conventional farm equipment. This can be accomplished by using the basic components of commercial application equipment in the design of the small-plot equipment. For example, nozzle types, sizes, and arrangements on small plot sprayers can be identical to those used by growers on commercial ground sprayers. Single-row commercial granular application equipment mounted on a garden tractor for small plot trials should produce results comparable to a multiple of such units on a large tractor. For large-scale field trials, commercial application equipment should be used. Specific details as to descriptions of equipment design, adjustment, and operation should be provided in test reports.
(g) **Evaluation and reporting requirements**—(1) **General.** (i) Experimental use permits may be required for the terrestrial testing of pesticides under field conditions involving more than 10 acres such as in studies described in OPPTS 850.4025 and 850.4300. A permit may be required for aquatic field testing of pesticides of more than 1 acre.
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(ii) The report should include a detailed and accurate description of test procedures, materials, results, and analysis of the data, a statement of conclusions drawn from the analysis, and a tabular summary and abstract of results. When they have been determined, the primary and secondary

modes of action with respect to plant morphogenic and biochemical levels should be reported.
(iii) The metric system should be used in test reports. The U.S. Standard Measures may be used to preclude extensive conversion to the metric system. The two systems cannot be mixed (e.g. grams per square feet).
(iv) The English language must be used in all test reports. English translations must be provided with foreign language reports.
(2) **Test materials and methods**—(i) **Dates.** Report the actual dates of the studies including dates of initiation (planting, transplanting, and cultural practices), applications, observations, and harvest.
(ii) **Laboratories.** The names of the laboratories or institutions performing the tests should be included.
(iii) **Personnel.** Name and title of each investigator, and the name, address, and phone number of the employer must be reported.
(iv) **Test substance.** Identification of the test substance must be provided, including:
(A) Chemical name, molecular structure, and qualitative and quantitative determination of its chemical composition.
(B) Relevant properties of the substance tested, such as physical state, pH, and stability.
(C) General identification and composition of any vehicles (e.g. diluents, suspending agents, and emulsifiers) or other materials used in the testing of the substance.
(D) Appropriate portions of this reporting requirement may be satisfied by cross-referencing to OPPTS Series 830 (Product Properties Test Guidelines).
(v) **Untreated control (check) plots.** Detailed descriptions of plots and plants used as controls for comparisons of toxic effects should be included for each test. Untreated control (check) plots should be treated and evaluated in the same manner as the treatment plots with respect to other pesticides or chemical (fertilizers, etc.) and cultural practices.
(vi) **Test organisms.** The description should include the identification of the test organisms (genus, species, and cultivar or variety, as appropriate), rationale for selection of the species employed, and location of plant collection areas including their physiographic data. When plant spe**9** cies other than those identified for specific studies have been tested, their degree of susceptibility to the pesticide should be included in the test report. This susceptibility should be reported in terms of EC values as in the regular test plant reports.
(vii) **Location.** Geographic location, including relation to the target sites, should be reported.
(viii) **Substrate conditions.** (A) For aquatic pesticide applications, the following physiographic conditions should be reported:
(*1*) Type of aquatic site, such as lake, pond, reservoir, stream, or irrigation

ditch with flow rate (if moving water).
(*2*) Size (area and depth or volume or length, width, and depth of the treated areas, and of the whole site), as is appropriate to the type of application and the type of target organisms.
(*3*) Water quality, including pH, temperature, hardness, alkalinity or salinity, where possible.
(*4*) Turbidity (visual), conductivity (if possible), and dissolved oxygen (for submerged plants only).
(*5*) Soil texture, including that of soils along the immediate shoreline or ditchbank and the submerged soil where the target pests are present (with the percent organic material in the soil also reported). (Recommended methods and soil texture classifications may be found in paragraph (i)(3) of this guideline.
(B) For terrestrial pesticide applications, the following physiographic conditions should be included:
(*1*) The edaphic conditions and characterization including soil type and texture, approximate pH and temperature, and K_d, and K_{ow} values.
(*2*) Where the presence of a fragipan or shallow bedrock may lead to restricted leaching or soil waterflow, the depth of that restriction.
(*3*) The degree and direction of slope and its orientation to the row direction if the slope will lead to excessive runoff.
(ix) **Environmental conditions.** (A) For growth chambers and laboratory experimentation, the light quality, light quantity (lux), air temperature, humidity, photo- and thermoperiods, and watering schedules should be reported.
(B) For greenhouse and field experiments, the approximate light quantity (usually expressed in degree of cloudiness), high and low daily air temperatures, relative humidity, and photoperiod (day length) should be reported. The environmental conditions of the specific field site are

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required only for the day of application. Area or specific field environmental conditions may be used for long term studies. Rainfall is to be reported for the duration of field experiments.
(x) **Application**—(A) **General.** The test substance application method

should be reported, including dosage rates, application equipment (nozzle, orifice, pressure), time and number of applications with reference to season and stage of growth), spray dilution, spray volume per unit area, and adjuvants.

(B) **Application rates.** Dosages should be reported in units of AI or acid equivalent as appropriate. Rates may be expressed as units of ingredient per unit of land area to be treated, units of concentration (such an parts per million), units per flow rate, or units of ingredient per unit volume applied to obtain a specified degree of foliage coverage (such as to runoff). If a product is applied more than once within a year or growing season, each rate and the interval between applications should be indicated. If products are applied in a tank mixture or are applied serially, rates and intervals, as appropriate, should be reported with identification and formulation for each product.

(C) **Timing of applications.** When the test substance, particularly a herbicide, plant regulator, desiccant, or defoliant, is applied to any desirable nontarget plants within or adjacent to the target area, the stage of growth or development of the plants at application should be described in test reports.

(D) **Serial applications.** In addition to the detrimental effects of the pesticides, the times of application (or application interval) should be indicated for each product or tank mix involved in the serial application.

(3) **Observations.** (i) Observations should be reported to include all variations, either inhibitory or stimulatory, between the treated test organisms and the untreated control test organisms. Such variations may be phytotoxic symptoms (chlorosis, necrosis, and wilting), formative (leaf and stem deformation) effects, and/or growth and development rates. Observations should include the stage of development and dates when adverse results occurred and subsided or recovered. Any lack of effects by the pesticide should also be reported.

(ii) Observations should be reported in sufficient detail to allow complete evaluation of the results. This evaluation, to be performed by the registrant, should include the degree or extent of effects exerted by the pesticide in question for each replicate and variable.

(iii) The detrimental or adverse effects to be considered and reported during the observation period of terrestrial studies include:

(A) Stand or plant population.

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(B) Overall vigor of the plants expressed as height, weight, diameter, length, or other similar aspect of growth.

(C) Phytotoxicity or visible symptoms such as discoloration, malformation, desiccation, or defoliation.

(D) Lodging of plants.
(E) Effect on root growth and structure.
(F) Development delay or acceleration with respect to maturation.
(G) Yield of the crop or commodity that is treated as compared to those of crops or commodities of untreated check plots.
(iv) Where pesticides are applied to aquatic systems and influence plant growth and development in aquatic systems, the effects of that pesticide on nontarget plants in the system and along the immediate border should be evaluated and reported, including vigor of the plants, phytotoxicity or other visible symptoms, and delay or acceleration with respect to vegetative growth, flowering or sporulation, and maturation.
(v) Uniform scoring procedures should be used to evaluate the observable toxic responses.
(vi) At least two methods of evaluation (such as quantitative and qualitative determinations) should be used in the evaluation of pesticide effects on growth, reproduction, and yield of plants in greenhouse and controlled chamber experiments. When direct measurements cannot be made, such as in large field evaluations, a 0 to 100 or 0 to 10 rating scale should be used, where 0 indicates no injury and 100 or 10 indicates a total effect or kill produced by the test substance. An explanation of the steps of the rating scale employed should be included with the report.
(vii) Observation reports should include the basic data to be used for the statistical analysis (see paragraph (g)(4) of this guideline). Such data should include the actual values used to determine any percentages of effects. Raw data (chromatographs, field reports, and analysis data) may also be included to substantiate the basic data that are required.
(4) **Statistical analysis.** (i) When test results such as efficacy, phytotoxicity, or yield indicate adverse effects on crops and other nontarget test organisms, statistical analysis is required in the evaluation the responses. The statistical analysis should consist of:
(A) The tabulation of the response data at each treatment level.
(B) The determination of 25 or 50 percent detrimental effect levels (e.g. EC25, EC50, as appropriate) and the 95 percent confidence limits, where possible, for each.

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(C) The estimated nondiscernible effect level. This is the level at which there would be no significant effect on the intended yield, quality, or aesthetics of the crop or plant which might be exposed.
(ii) Statistical analysis is also useful in evaluation of interactions resulting

from studies supporting tank mixtures or serial applications.
(5) **Supporting material.** Copies of references or literature used in modifying the test protocol, performing the test, making and interpreting observations, and compiling and evaluating the results should be submitted. Copies of unpublished literature should also be included. Copies of the recommended literature referenced in these guidelines are not required.
(6) **Special test requirements.** In addition to the data required in this guideline, data from other tests may be required by the Agency for making judgments regarding safety to nontarget plants. Such data will be required where there are special problems, such as a proposed pattern of use, mode of phytotoxic action, or a unique chemical property. Methods are usually derived from those already described or cited in other guidelines.
(h) **Reporting elements for acceptability.** (Further details are provided in each guideline.)
(1) Information to be provided regarding the nontarget plant phytotoxicity screening data:
(i) Mode of action (if available).
(ii) Common and Latin names of species tested.
(iii) Species should be tested with a minimum of five doses bracketing NOEC and EC50 (or effect at maximum label rate for species not responding).
(iv) Calculation of a dose-response curve with NOEC, EC05, EC25, EC50, slope, and CI (confidence interval) for each species.
(v) Raw data preferably in electronically readable form.
(2) Documentation to be provided on testing procedures.
(i) Application method (ppi, pre-, post-emergence).
(ii) Test substance and doses used (AI, end-use product, adjuvant used).
(iii) Indoor vs. outdoor trials.
(iv) Number of replicates per dose (minimum of three).
(v) Number of plants per dose (number of plants per pot).
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(vi) Endpoints used (definition of rating scales, quantitative or qualitative precision).
(vii) Seed source, stage of the plant life cycle (seed, seedling, leaf stages).

(viii) Date and duration of testing, soil type.
(ix) Bottom vs. top watering and frequency of watering.
(x) Any other relevant information pertinent to the evaluation.
(i) **References.** The following references should be consulted for additional background material on this test guideline.
(1) Boutin, C. et al. Proposed Guideline for Registration of Chemical Pesticides: Nontarget plant testing and evaluation. Technical Report Series No. 145, Canadian Wildlife Service, Environment Canada, pp. 1 - 91 (1993).
(2) Truelove, B., (ed). *Research Methods in Weed Science*. Southern Weed Science Society. Auburn Printing Inc., Auburn, AL (1977)
(3) U.S. Department of Agriculture. Soil Survey Manual, Handbook No. 18 (1951).

Appendix 3

Regluatory documentation relative to Para. 3 of the EPA letter

Title 40—Protection of Environment

(This index contains parts 150 to 189)
CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

Part
150-151 [Reserved]
152 Pesticide registration and classification procedures
153 Registration policies and interpretations
154 Special review procedures
155 Registration standards
156 Labeling requirements for pesticides and devices
157 Packaging requirements for pesticides and devices
158 Data requirements for registration
159 Statements of policies and interpretations
160 Good laboratory practice standards
162 State registration of pesticide products
163 Certification of usefulness of pesticide chemicals
164 Rules of practice governing hearings, under the Federal Insecticide, Fungicide, and Rodenticide Act, arising from refusals to register, cancellations of registrations, changes of classifications, suspensions of registrations and other hearings called pursuant to section 6 of the Act
166 Exemption of Federal and State agencies for use of pesticides under emergency conditions
167 Registration of pesticide and active ingredient producing establishments, submission of pesticide reports
168 Statements of enforcement policies and interpretations
169 Books and records of pesticide production and distribution
170 Worker protection standard
171 Certification of pesticide applicators
172 Experimental use permits
173 Procedures governing the rescission of State primary enforcement responsibility for pesticide use violations
177 Issuance of food additive regulations
178 Objections and requests for hearings
179 Formal evidentiary public hearing
180 Tolerances and exemptions from tolerances for pesticide chemicals in food
185 Tolerances for pesticides in food
186 Pesticides in animal feed
187-189 [Reserved]

The following information is reproduced below, from
Ref: http://a257.g.akamaitech.net/7/257/2422/08aug20031600/edocket.access.gpo.gov/cfr_2003/julqtr/pdf/40cfr158.202.pdf

Acute studies.

Determination of
acute oral, dermal and inhalation toxicity
is usually the initial step in the
assessment and evaluation of the toxic
characteristics of a pesticide. These
data provide information on health
hazards likely to arise soon after, and
as a result of, short-term exposure.
Data from acute studies serve as a
basis for classification and precautionary
labeling. For example,
acute toxicity data are used to calculate
farmworker reentry intervals
and to develop precautionary label
statements pertaining to protective
clothing requirements for applicators.
They also: provide information used in
establishing the appropriate dose levels
in subchronic and other studies; provide
initial information on the mode of
toxic action(s) of a substance; and determine
the need for child resistant
packaging. Information derived from
primary eye and primary dermal irritation
studies serves to identify possible
hazards from exposure of the eyes, associated
mucous membranes and skin.

The estimated cost of studies of this magnitude is 3 to 4 man-years, at an estimated cost of perhaps $400,000 to $500,000.

Appendix 4

(reserved)

Appendix 5

Regluatory documentation relative to Para. 5 of the EPA letter

Label Review Manual Table of Contents

Chapter	Available as PDF	Updated
1. Purpose of Manual	PDF Version (3 pp, 39KB, about PDF)	December 2006
2. What is a Pesticide?	PDF Version (11 pp, 101KB, about PDF)	December 2006
3. General Labeling Requirements	PDF Version (18 pp, 164KB, about PDF)	December 2006
4. Types of Label Reviews	PDF Version (12 pp, 100KB about PDF)	August 2007
5. Ingredient Statement	PDF Version (15 pp, 120KB about PDF)	August 2007
6. Use Classification	PDF Version (5 pp, 60KB about PDF)	August 2007
7. Precautionary Labeling	PDF Version (18 pp, 199KB about PDF)	August 2007
8. Environmental Hazards		August 2003
9. Physical or Chemical Hazards	PDF Version (6 pp, 64KB about PDF)	September 2007
10. Worker Protection Labeling		August 2003
11. Directions for Use		August 2003
12. Labeling Claims	PDF Version (12 pp, 113Kb, about PDF)	November 2007
13. Storage and Disposal		August 2003
14. Identification Numbers	PDF Version (6 pp, 71Kb, about PDF)	January 2008
15. Company Name and Address	PDF Version (4 pp, 51Kb, about PDF)	January 2008
16. Graphic & Symbols on Labels		August 2003
17. Content/Net Weight Statement		August 2003
18. Unique Product Labeling		August 2003
19. The Consumer Labeling Initiative and Pesticide Labels		August 2003

Questions on Pesticides?

- National Pesticide Information Center (NPIC) 1-800-858-7378

Labeling Resources

- Pesticide Labeling Consistency
- Globally Harmonized System (GHS) of Classification and Labelling

The Agency is interested in optimizing the usefulness of the Label Review Manual (LRM) as a tool for understanding the pesticide labeling process. The LRM is also useful in understanding approaches for how labels should generally be drafted. As always, the Agency will consider each label on its own merits and will consider deviations from Agency policy in labeling under the appropriate provisions of FIFRA and its implementing regulations.

EPA considers this document to be an instructional aid that does not establish new guidance, but instead compiles extant interpretations of statutory and regulatory provisions and reiterates existing Agency policies.

Errors or suggestions for the LRM can be submitted to the Agency at our Pesticide Labeling Consistency Web site, Pesticide Labeling Questions and Answers page.

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